



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

6382 '02 MAR 26 P2:20

MAR 12 2002

Mr. Armando S. Trevino
A&A Customs Brokerage Services, Inc.
807 Produce Road, Suite A
Hidalgo, Texas 78557

Dear Mr. Trevino:

This is in response to your submission to the Food and Drug Administration (FDA), dated January 28, 2002. Your submission appears to be intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) (see also 62 FR 49883; September 23, 1997) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not state that you or a responsible person of the manufacturer or distributor certifies that the firm is in compliance with the requirements of the Act and the regulation, including the requirement that the firm have substantiation that the claims it is making for this product are truthful and not misleading. Therefore, the firm responsible for distribution of the subject product has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification in accordance with the requirements in 21 CFR 101.93(a), including the requirement in 21 CFR 101.93(a)(3).

975-0163

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Page 2 - Mr. Armando S. Trevino

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret", followed by a long horizontal line and a small flourish.

John B. Foret
Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

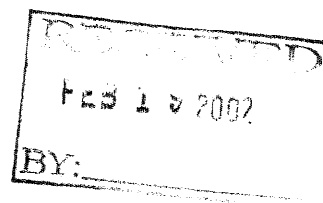
FDA, Florida District Office, Compliance Branch, HFR-SE240

28 JAN. 02

NOTIFICATION

79325-

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.
Washington, D.C. 20204



Dear Sirs:

This is to advise that the following named company will be the importer and distributor of a dietary supplement known as "Long Life Colostrum Gold Plus" produced and packed in New Zealand:

Manufacturer: **Functional Nutraceuticals, Ltd.**
P.O. Box 164
Morrinsville, New Zealand

Distributor : **Long Life Gold, Inc.**
2604 N.W. 97 Ave.
Miami, Fla. 33172
Phone (305) 716-5080

The product to be imported will be in both capsule (480 mg) and powder form (200gms) in plastic containers. Capsules will indicate "Increased 100% effectiveness. Helps support immune function while helping to fortify the health and maintenance of the Gastrointestinal System." The powder form will indicate, " Supports immune function. Helps to increase vitality and stamina. Powerful naturally anti-aging."

As provided under 201(g) (1) (C) of the Federal Food, Drug, and Cosmetic Act, the following disclaimer will be included on each label that "this statement(s) has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

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Additionally, the disclaimer, as provided by the act, shall appear on each panel or page where there is such a statement. In accordance with requirements, typesize of the lettering shall appear in boldface no smaller than one- sixteenth inch.

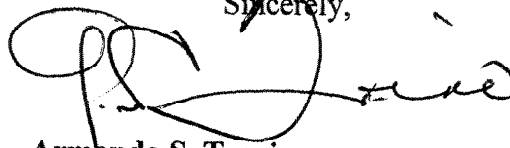
In support of our letter, we herewith submit additional data from the New Zealand manufacturer regarding, inter alia, the quality of the product and it recommended usage, etc.:

- (1.) Health Certificate**
- (2.) New Zealand's position with regard to BSE**
- (3.) New Zealand's freedom from foot and mouth disease**
- (4.) Free sale certificate - Public Health**
- (5.) Affidavit certificate of quality, health and New Zealand origin**
- (6.) Certificate of analysis**
- (7.) Certificate of origin and health**

As the intermediate consignee, we, the U.S. Customs Broker Agency, have been designated under power of attorney, CF5291, to represent this client on matters involving the importation of the subject product, and our client has, also, extended the authorization for as to transfer the foregoing range of information to the Food and Drug Administration.

Accordingly, we would be glad to assist in any manner in exchange of any further information with our client should it be necessary.

Sincerely,



Armando S. Trevino
A&A Customs Brokerage Services Inc.
807 Produce Road, Suite A
Hidalgo, Texas 78557
(956) 843-8464/65/66